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Hazy Definition Of Pot Edibles Creates Regulatory Void

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Nearly 20 years ago, California voters approved the Compassionate Use Act of 1996, also known as Proposition 215, making California the first state to legalize cannabis for medicinal purposes. Smoking continues to be the most common method of consuming medicinal cannabis, but edible cannabis products in the form of chewing gum, cookies, brownies, bars, cakes, etc. are a growing part of the market. Proposition 215 did not set forth any rules or regulations governing the production and sale of medicinal cannabis and there is now a question whether existing federal and/or California food safety laws and regulations will govern the making and selling of edible cannabis products within the state.

On Oct. 9, 2015, California Gov. Jerry Brown signed the Medical Marijuana Regulation and Safety Act (MMRSA), which becomes effective Jan. 1, 2016. MMRSA amended the California Business and Professions Code to establish a comprehensive state licensing system for the commercial cultivation, manufacture, sale, distribution, delivery and testing of medicinal cannabis, including edible cannabis products. The MMRSA defines an edible cannabis product as follows:

> "Edible cannabis product" means manufactured cannabis that is intended to be used, in whole or in part, for human consumption, including, but not limited to, chewing gum. An edible medical cannabis product is not considered food as defined by Section 109935 of the Health and Safety Code or a drug as defined by Section 109925 of the Health and Safety Code.

This language appears to exempt edible cannabis products from California's food safety laws and regulations governing conventional foods. Earlier drafts of the MMRSA prescribed basic food safety handling and manufacturing procedures and included sanitation standards equivalent to the California Retail Food Code, which were to be enforced by the California Department of Public Health. As enacted, the MMRSA includes some limited requirements for laboratory testing of edible cannabis products to ensure that such products do not contain foreign materials such as hair or insects, or microbiological "impurities" such as mold, aureus bacterium or aflatoxins. But the MMRSA does not specify that edible cannabis products must be tested for common foodborne pathogens such as salmonella, listeria or E coli. Further, because the MMRSA provides that edible cannabis products are not considered "food," such products are not technically subject to state food safety requirements for sanitary manufacturing facilities or inspections of manufacturing facilities by the California Department of Public Health.

The food exemption in the MMRSA has created something of a regulatory void. A section of the MMRSA provides that "the state department of public health shall develop standards for the production and labeling of all edible medical cannabis products," but it does not provide a deadline for the California Department of Public Health to develop and implement those standards.

Further, it is unclear what role the federal government may take to regulate the safety of edible cannabis products. The U.S. Food and Drug Administration has not, to date, enforced federal food safety laws on those manufacturing edible cannabis products. Possession and sale of cannabis remains illegal under federal law, in any form, and it is unclear how the FDA will interpret its

regulatory mandate in the context of edible cannabis products that contain an ingredient classified as a Schedule I drug under the federal Controlled Substances Act. Under the Supremacy Clause of the United States Constitution, the FDA is unlikely to give credence to the MMRSA's definition of edible cannabis products as "not food" and "not a drug." This could prompt the FDA to consider cannabis an adulterant, which in turn could encourage the FDA to shut down any facility producing edible cannabis products. Even if the FDA does not address the issue of whether cannabis is an adulterant, it will be concerned that commercial operations that manufacture and sell edible cannabis products operate as safely as those manufacturing and selling conventional foods. The agency may be willing to look the other way with respect to cannabis, but it will not do so if these products cause foodborne illness.

Rather than waiting for legislators or regulators to impose food safety standards for edible cannabis products, California manufacturers and producers of such products should educate themselves regarding the federal laws and regulations that apply to the conventional forms of food now being used as vehicles for the consumption of cannabis and apply those standards to their production process. Manufacturers and producers can also seek guidance from states such as Washington, which enacted regulations to reduce the risk that marijuana-infused foods will cause foodborne illnesses. For example, Washington has limited the food items into which marijuana can be infused and it requires processors to pass regular facility inspections.

By ensuring that their production operations conform to established food safety and regulatory standards, manufacturers and producers will reduce the risk that their products will cause harm to consumers, via foodborne illness. This will provide enhanced protection for consumers of edible products, many of whom often have weakened immune systems and may be at increased risk of developing an infectious disease. It will also help manufacturers and producers to lessen the chance that they will be sued for providing contaminated products to consumers. Further, adopting and complying with food safety standards may lessen the chance that federal regulators will be compelled to intervene and exercise their enforcement powers. Finally, strict compliance with food safety standards will help protect the legitimacy of these products as medical treatment.

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